Appendix A

Claim Amendments

1. (Currently amended) $\frac{Process}{A}$ $\frac{A}{Process}$ for preparing a compound of the formula I

in crystalline form, with defined particle size, comprising the steps of

- a) preparation of preparing a solution of the compound of the formula I in a suitable water-miscible organic solvent;
- b) adding the solution obtained [[as]] in a) to water and
- c) isolating [[the]] <u>a</u> precipitate of the compound of the formula I which is formed.

- 2. (Currently amended) Process The process according to Claim 1, characterized in that the suitable watermiscible organic solvent is an alcohol.
- 3. (Currently amended) Process The process according to Claim 2, characterized in that the alcohol is selected from the group consisting of methanol, ethanol, N-propanol, [[and]] isopropanol [[or]] and mixtures in any mixing ratio thereof.
- 4. (Currently amended) Process The process according to Claim 3, characterized in that the alcohol is ethanol is involved.
- 5. (Currently amended) Process The process according to Claim 1, characterized in that the suitable water-miscible organic solvent is selected from the group consisting of acetone, tetrahydrofuran [[or]] and dimethylformamide is involved.
- 6. (Currently amended) <u>Process</u> <u>The process</u> according to Claim 1, characterized in that the temperature of the suitable water-miscible organic solvent is in the range

from 15°C to 10°C below the boiling point of the solvent.

- 7. (Currently amended) Process The process according to Claim 6, characterized in that the temperature of the suitable water-miscible organic solvent corresponds to the room temperature at which the process is carried out.
- 8. (Currently amended) Process The process according to Claim 1, characterized in that the temperature of the water is from 10 to 50°C.
- 9. (Currently amended) Process The process according to Claim 7, characterized in that the temperature of the water corresponds to the room temperature at which the process is carried out.
- 10. (Currently amended) Process The process according to Claim 1, characterized in that the compound of the formula I has the chemical name 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione [11beta,

16alpha (R,S)].

- 11. (Currently amended) Process The process according to Claim 1, characterized in that the compound of the formula I is substantially in the form of the R epimer.
- 12. (Currently amended) Process The process according to Claim 11, characterized in that the proportion of R epimer in the compound of the formula I is more than 95%.
- 13. (Currently amended) Process The process according to Claim 11, characterized in that the compound of the formula I is ciclesonide is involved.
- 14. (Currently amended) <u>Process</u> <u>The process</u> according to Claim 1, characterized in that the precipitate obtained [[after]] <u>in</u> step c) is subsequently dried.
- 15. (Currently amended) Process The process for preparing a compound of the formula I according to Claim 1 in crystalline form with defined particle size, comprising the steps of

a) preparing a compound of the formula I by acylation of a compound of the formula II

$$\begin{array}{c} O \\ O \\ O \\ O \\ A \\ \end{array}$$

$$\begin{array}{c} O \\ CH_3 \\ \hline \\ H \\ \end{array}$$

$$\begin{array}{c} O \\ 13 \\ \hline \\ 10 \\ \hline \\ \end{array}$$

$$\begin{array}{c} O \\ 13 \\ \hline \\ 10 \\ \hline \\ \end{array}$$

$$\begin{array}{c} O \\ 13 \\ \hline \\ \\ \end{array}$$

$$\begin{array}{c} O \\ 13 \\ \hline \\ \\ \end{array}$$

$$\begin{array}{c} O \\ 16 \\ \hline \\ \end{array}$$

$$\begin{array}{c} O \\ 22 \\ \hline \\ \end{array}$$

$$\begin{array}{c} O \\ 22 \\ \hline \\ \end{array}$$

$$\begin{array}{c} O \\ A \\ \hline \\ \end{array}$$

with a suitable acylating agent;

- b) crystallizing the compound of the formula I obtained in a) by adding water to a solution of the compound in a suitable water-miscible organic solvent or heating a suspension of the compound of the formula I in a mixture of a suitable water-miscible organic solvent and water,
- c) removing the resulting R epimer-enriched precipitate of the compound of the formula I from the water/solvent mixture;
- d) if desired repeating step b);
- e) preparing a solution of the compound obtained in c) in a suitable water-miscible organic solvent;

- f) adding the solution obtained [[as]] in e) to water and
- g) isolating [[the]] \underline{a} precipitate which has been formed of the compound of the formula I.
- 16. (Currently amended) Process The process according to Claim 1, where the particle size is characterized by an X_{50} of less than or equal to 10.
- 17. (Currently amended) Process The process according to Claim 16, where the particle size is characterized by an X_{50} [[of]] in the range from 1.8 to 2.0.
- 18. (Currently amended) Process The process according to Claim 15, where the organic solvents used in steps b) and e) are the same solvents.
- 19. (Currently amended) Compound A compound of the formula I obtainable according to the process of Claim 1 without a further micronization step, where the compound is in inhalable form.

- Claim 19, where the particle size of wherein the compound of the formula I has a particle size characterized by an X_{50} in the range from 1.8 to 2.0.
- 21. (Currently amended) Compound The compound according to claim 19 Claims 19 or 20, which compound is not in micronized form.
- 22. (Currently amended) Crystalline A crystalline ciclesonide with a particle size characterized by an X_{50} of less than or equal to 10.
- 23. (Currently amended) Crystalline A crystalline ciclesonide with a particle size characterized by an X_{50} [[of]] in the range from 1.8 to 2.0.
- 24. (Currently amended) Crystalline

 ciclesonide according to claim 22 Claims 22 or 23, which

 ciclesonide is not in micronized form.
- 25. (Currently amended) Pharmaceutical A pharmaceutical composition comprising a compound according to claim 19

 Claims 19 to 24, which compound is present as solid

particles together with <u>one or more</u> pharmaceutically acceptable excipients.

- 26. (Currently amended) Pharmaceutical A pharmaceutical composition according to claim 25, which is an aqueous suspension of the compound.
- 27. (Currently amended) Pharmaceutical A pharmaceutical composition according to claim 25, which is a dry powder.